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Section II (Remarks)

The undersigned extends appreciation to the examiner for identifying subject matter embodying patentable distinctions over the prior art. (May 10, 2007 Office Action, pages 9-10.) Such action is helpful to expedite prosecution of the instant application without undue guesswork by the Applicant.

A. Summary of Amendment to the Claims

By the present Amendment, claims 9, 12, 13, 19, 27, 31, 32, 37, 44, 49, 52, and 54 have been amended. New claim 63 has been added. Claims 1-8 were previously cancelled. No new matter within the meaning of 35 U.S.C. §132(a) has been introduced by the foregoing amendments.

The amendments made herein are fully consistent with and supported by the originally-filed disclosure of this application.

B. Subject Matter Indicated as Allowable

Applicant acknowledges the indication by the examiner that claims 55-62 are allowable, and that claims 11 and 30 would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. (May 10, 2007 Office Action, pages 9-10.) New claim 63 embodies the subject matter of former claim 11 (i.e., as depending from former claim 9), rewritten in independent form (see line 7 of such claim, reciting "a gas that is more than about 95% sterile"). In view of the Examiner's acknowledgement that claim 11 would be allowable if rewritten in independent form, the corresponding new independent claim 63 is believed to be allowable.

B. Rejection of Claims Under 35 USC § 102

In the May 10, 2007 Office Action, claims 9, 10, 12, 13, 17-29, 31-34, 36-45, 47-54 were rejected under 35 USC §102(b) as being anticipated by U.S. Patent No. 5,122,129 to Olson, et al. ("Olson"). Such rejections are traversed in application to the claims as amended herewith.

1. Law Regarding Anticipation Rejections under 35 U.S.C. § 102

"Anticipation requires the disclosure in a single prior art reference of each element of the claim under consideration." *W.L. Gore & Assocs. v. Garlock*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed.

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Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). It is not enough that the prior art reference disclose all the claimed elements in isolation. Rather, "anticipation requires the presence in a single prior art reference disclosure of each and every element of the claimed invention, arranged as in the claim." *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (emphasis added). Further, "[u]nder 35 U.S.C. § 102, anticipation requires that ... the prior art reference must be enabling, thus placing the allegedly disclosed matter in the possession of the public." *Akzo, N.V. v. United States Int'l Trade Comm'n*, 808 F.2d 1471, 1 USPQ2d 1241, 1245 (Fed. Cir. 1986).

2. Patentable Distinctions of Pending Claims Over Olson

The examiner has not identified any portion of Olson that teaches or suggests the presence of any "gas, when inside the housing chamber, has a pressure sufficient to generate a laminar flow outward from an opening defined in the membrane upon piercing of the membrane by the connector," as required by independent claims 9, 27, and 44. Indeed, the examiner has expressly indicated that a nearly identical limitation would patentably distinguish over the art of record in the instant application. See May 10, 2007 Office Action, pages 9-10, with proposed claim including "wherein ... the gas inside the housing chamber has a pressure sufficient to generate a laminar flow along the connector when the connector pierces the opening"

In view of the failure of Olson to teach the limitation added to claims 9, 27, and 44 as amended herewith, and the indication by the examiner that such limitation would patentably distinguish the claims over the art, independent claims 9, 27, and 44 are therefore distinguished over Olson. Because dependent claims inherently include all the limitations of the claims on which they depend, all claims depending (whether directly or indirectly) from independent claims 9, 27, and 44 are likewise distinguished over the art of record. Accordingly, withdrawal of the rejections under 35 U.S.C. 102 is warranted, and respectfully requested.

C. Rejection of Claims Under 35 USC § 103

In the May 10, 2007 Office Action, the examiner also rejected claims 9, 10, 12-26, 35, 44, 46 and 47 under 35 USC §103(a) as being unpatentable over Olson, et al (U.S. Patent No. 5,122,129) in view of Silverman (U.S. Patent 6,391,014).

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1. Law Regarding Obviousness Rejections Under 35 U.S.C. § 103

To support a rejection under 35 U.S.C. 103, the prior art reference(s) must teach all of the limitations of the claims. MPEP § 2143.03.

In considering a reference for its effect on patentability, the reference is required to be considered in its entirety, including portions of teach away from the invention under consideration. Simply stated, the prior art must be considered as a whole. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); MPEP § 2141.02. "It is impermissible within the framework of section 103 to pick and choose from any one reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *Application of Wesslau*, 353 F.2d 238, 241 (C.C.P.A. 1965); *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve*, 796 F.2d 443, 448 (Fed. Cir. 1986), *cert. denied*, 484 U.S. 823 (1987).

According to the recent U.S. Supreme Court decision in *KSR International Co. v. Teleflex Inc.*, No. 04-1350, 550 U.S. ____ (April 30, 2007), the court did not disavow the previous "teaching, motivation or suggestion" or "TSM" test, but stated that such TSM text *should not be strictly applied* in determining obviousness. In connection with this point, the Supreme Court stated that:

"A patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently, known in the prior art. ... [Rather], it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant art to combine the [prior art] elements in the manner claimed." *KSR*, slip op. at 14.

It is fundamental to a proper rejection of claims under 35 U.S.C. 103 that an examiner must present a convincing line of reasoning supporting the rejection. MPEP 2144 ("Sources of Rationale Supporting a Rejection Under 35 U.S.C. 103"), citing *Ex parte Clapp*, 227 USPQ 972 (Bd. Pat. App. & Inter. 1985). The Supreme Court in *KSR* affirmed the validity of such approach, stating that "there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness."

In *KSR*, the Supreme Court further confirmed that references that teach away from the invention are evidence of the non-obviousness of a claimed invention, (*KSR*, slip op. at pp. 20-23) and reaffirmed the principle that a factfinder judging patentability "should be aware, of course, of the

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distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning."

2. Patentable Distinctions of Pending Claims Over Olson and Silverman

The examiner has not identified any portion of either Olson or Silverman that teaches or suggests the presence of any "gas, when inside the housing chamber, has a pressure sufficient to generate a laminar flow outward from an opening defined in the membrane upon piercing of the membrane by the connector," as required by independent claims 9, 27, and 44. Indeed, the examiner has expressly indicated that a nearly identical limitation would patentably distinguish over the art of record in the instant application. See May 10, 2007 Office Action, pages 9-10, with proposed claim including "wherein ... the gas inside the housing chamber has a pressure sufficient to generate a laminar flow along the connector when the connector pierces the opening"

In view of the failure of Olson or Silverman to teach the limitation added to claims 9, 27, and 44 as amended herewith, and the indication by the examiner that such limitation would patentably distinguish the claims over the art, independent claims 9, 27, and 44 are therefore distinguished over Olson. Because dependent claims inherently include all the limitations of the claims on which they depend, all claims depending (whether directly or indirectly) from independent claims 9, 27, and 44 are likewise distinguished over the art of record. Accordingly, withdrawal of the rejections under 35 U.S.C. 102 is warranted, and respectfully requested.

D. Fees Payable For Added Claim

By the present amendment, one independent claim (also embodying one total claim) has been added. Accordingly, excess claim fees presently due and payable under 37 CFR 1.16(h) and 1.16(i) are calculated as $(1 \times \$100) + (1 \times \$50) = \$150.00$. Payment of such fee is authorized in the enclosed Credit Card Payment Form PTO-2038.

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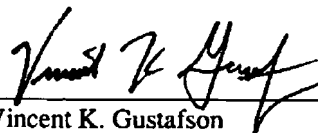
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CONCLUSION

Based on the foregoing, all of Applicant's pending claims 9-63 are patentably distinguished over the art, and in form and condition for allowance. The examiner is requested to favorably consider the foregoing, and to responsively issue a Notice of Allowance. If any issues remain and are amendable to telephonic resolution, the examiner is requested to contact the undersigned attorney at (919) 419-9350 to discuss same.

Respectfully submitted,



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